

IC 25-26-14**Chapter 14. Wholesale Legend Drug Distributors****IC 25-26-14-1**

Sec. 1. This chapter applies to any individual, partnership, limited liability company, corporation, or business firm engaging in the wholesale distribution of legend drugs within Indiana.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.394.

IC 25-26-14-2

Sec. 2. As used in this chapter, "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-3

Sec. 3. As used in this chapter, "blood component" means that part of blood separated by physical or mechanical means.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-4

Sec. 4. As used in this chapter, "board" refers to the Indiana board of pharmacy established under IC 25-26-13-3.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-5

Sec. 5. As used in this chapter, "drug sample" means a unit of a legend drug that is not intended to be sold and is intended to promote the sale of the drug.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-6

Sec. 6. As used in this chapter, "health care entity" means any organization or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-7

Sec. 7. As used in this chapter, "legend drug" has the meaning set forth in IC 16-18-2-199. The term includes any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to 21 U.S.C. 811 through 812.

As added by P.L.182-1991, SEC.3. Amended by P.L.2-1993, SEC.147.

IC 25-26-14-8

Sec. 8. As used in this chapter, "manufacturer" means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a legend drug.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-9

Sec. 9. As used in this chapter, "person" means an individual, a partnership, a business firm, a limited liability company, or a corporation.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.395.

IC 25-26-14-10

Sec. 10. As used in this chapter, "sale" includes purchase, trade, or offer to sell, purchase, or trade.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-11

Sec. 11. As used in this chapter, "wholesale distribution" means distribution of legend drugs to persons other than a consumer or patient. The term does not include:

- (1) a sale between a division, a subsidiary, a parent, an affiliated, or a related company under the common ownership and control of a corporate entity;
- (2) the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of the organization;
- (3) the sale of a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (4) the sale of a drug among hospitals or other health care entities that are under common control;
- (5) the sale of a drug for emergency medical reasons, including transfers of legend drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfers does not exceed five percent (5%) of the total legend drug sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period;
- (6) the sale of a drug or the dispensing of a drug pursuant to a prescription;
- (7) the distribution of drug samples by manufacturers' representatives or distributors' representatives;
- (8) the sale of blood and blood components intended for transfusion;
- (9) the sale of a drug by a retail pharmacy to a practitioner (as defined in IC 25-26-13-2) for office use, if the gross dollar value of the transfers does not exceed five percent (5%) of the retail pharmacy's total legend drug sales during any twelve (12) consecutive months; or
- (10) the sale of a drug by a retail pharmacy that is ending its business and liquidating its inventory to another retail pharmacy.

As added by P.L.182-1991, SEC.3. Amended by P.L.33-1993, SEC.47.

IC 25-26-14-12

Sec. 12. As used in this chapter, "wholesale drug distributor" means a person engaged in wholesale distribution of legend drugs, including:

- (1) manufacturers;
- (2) repackers;
- (3) own-label distributors;
- (4) private-label distributors;
- (5) jobbers;
- (6) brokers;
- (7) warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;
- (8) independent wholesale drug traders; and
- (9) retail and hospital pharmacies that conduct wholesale distributions.

The term does not include a common carrier or person hired solely to transport prescription drugs.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-13

Sec. 13. The board shall adopt rules under IC 4-22-2 that conform with wholesale drug distributor licensing guidelines adopted by the United States Food and Drug Administration (21 CFR 205), including rules:

- (1) necessary to carry out the purposes of this chapter;
- (2) that incorporate and set detailed standards for meeting each of the license prerequisites set forth in this chapter; and
- (3) establishing reasonable fees to carry out this chapter.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-14**YAMD.1991**

Sec. 14. (a) After September 14, 1992, a person may not engage in wholesale distributions of legend drugs without having a license from the board and paying any reasonable fee required by the board.

(b) The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter.

(c) The board may require a separate license for:

- (1) each facility directly or indirectly owned or operated by the same business in Indiana; or
- (2) a parent entity with divisions, subsidiaries, or affiliate companies in Indiana when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities.

(d) An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.

(e) The issuance of a license under this chapter does not affect tax liability imposed by the department of state revenue or the state board of tax commissioners on any wholesale drug distributor.

(f) The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if:

- (1) an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter; and
- (2) the other state extends reciprocity to wholesale drug distributors licensed in Indiana.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-15

Sec. 15. (a) The board shall require the following minimum information from each wholesale drug distributor as part of the license described in section 14 of this chapter and as part of any renewal of such license:

- (1) The name, full business address, and telephone number of the licensee.
- (2) All trade or business names used by the licensee.
- (3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of legend drugs.
- (4) The type of ownership of operation.
- (5) The name of each owner and operator of the licensee, including:
 - (A) if an individual, the name of the individual;
 - (B) if a partnership, the name of each partner, and the name of the partnership;
 - (C) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;
 - (D) if a limited liability company, the name of each manager and member, the name of the limited liability company, and the name of the state where organized; and
 - (E) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity.
- (6) The name of the person designated by the licensee as responsible for the operation of the facilities.

(b) A material change in any information in subsection (a) of this section must be submitted to the board at the time of license renewal or within thirty (30) days from the date of the change, whichever occurs first.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.396.

IC 25-26-14-16

Sec. 16. In reviewing the qualifications of persons who engage in wholesale distribution of legend drugs within Indiana, the board shall consider the following factors:

- (1) A conviction of the applicant relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances.
- (2) A felony conviction of the applicant.

- (3) The applicant's past experience in the manufacture or distribution of legend drugs, including controlled substances.
- (4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution.
- (5) Suspension or revocation by the federal or a state government of any license held by the applicant for the manufacture or distribution of any drugs, including controlled substances.
- (6) Compliance with licensing requirements under previously granted licenses.
- (7) Compliance with requirements to maintain and make available to the board or to federal, state, or local law enforcement officials those records required under this chapter.
- (8) Any other factors or qualifications the board considers relevant to the public health and safety, including whether the granting of the license would not be in the public interest.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-17

Sec. 17. As a condition for receiving and retaining any wholesale drug distributor license issued under to this chapter, each applicant must satisfy the board that the applicant has and will continuously maintain the following:

- (1) Acceptable storage and handling conditions and facilities standards.
- (2) A security system that includes:
 - (A) an after hours central alarm or a comparable entry detection capability;
 - (B) restricted premises access;
 - (C) adequate outside perimeter lighting; and
 - (D) safeguards against employee theft.
- (3) A reasonable system of recordkeeping that:
 - (A) describes all the wholesale distributor's activities governed by this chapter for the two (2) year period after the disposition of each product; and
 - (B) is reasonably accessible as determined by board rules in any inspection authorized by the board.
- (4) Written policies and procedures that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including:
 - (A) those caused by natural disaster or government emergency;
 - (B) inventory inaccuracies or product shipping and receiving;
 - (C) outdated product;
 - (D) appropriate disposition of returned goods; and
 - (E) product recalls.
- (5) Sufficient inspection procedures for all incoming and outgoing product shipments.
- (6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-18

Sec. 18. Any applicant denied a license or renewal under this chapter has the right of review of the board's action under IC 4-21.5.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-19

Sec. 19. (a) A person authorized by the board may enter and inspect, during normal business hours, all open premises that appear to be used by a wholesale drug distributor.

(b) Wholesale drug distributors may keep records regarding purchase and sales transactions at a central location apart from the principal office of the wholesale drug distributor or the location where the drugs were stored and from which the drugs were shipped, if the records are made available for inspection within two (2) working days of a request by the board. The records may be kept in any form permissible under federal law applicable to legend recordkeeping.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-20

Sec. 20. A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-21

Sec. 21. (a) A wholesale drug distributor license expires at midnight of the renewal date specified by the health professions bureau under IC 25-1-5-4 in each even-numbered year.

(b) The board shall mail renewal application forms to each licensed wholesale drug distributor before the first day of the month before the month in which the license expires. If an application for renewal has not been filed and the required fee paid before the license expiration date, the wholesale drug distributor license shall lapse and become void.

(c) A lapsed license may be reinstated only by paying all renewal fees and, if the license has lapsed for more than thirty (30) days, a late fee.

(d) A wholesale drug distributor may not be open for business after the license has lapsed, until the renewal is completed.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-22

Sec. 22. (a) The board, upon a showing of a violation of this chapter, may revoke, suspend, or limit a license issued under this chapter after a proceeding under IC 4-21.5.

(b) After a proceeding under IC 4-21.5, the board may assess a civil penalty against a licensed wholesale drug distributor of not more than one thousand dollars (\$1,000) for each occurrence. If the licensed wholesale drug distributor fails to pay the civil penalty within the time specified by the board, the board may suspend the license without additional proceedings.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-23

Sec. 23. A person that knowingly purchases or receives a legend drug from any source other than a person licensed under this chapter, including a wholesale distributor, manufacturer, pharmacy distributor, or pharmacy commits a Class A misdemeanor. A subsequent unrelated violation of this section is a Class D felony.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-24

Sec. 24. (a) Upon application by the board, a circuit or superior court may grant an injunction, a restraining order, or other order to enjoin a person from offering to engage or engaging in the performance of any practices for which a permit or license is required by any applicable federal or state law including this chapter, upon a showing that the practices were or are likely to be performed or offered to be performed without a permit or license.

(b) An action brought under this section must be commenced either in the county where the conduct occurred or is likely to occur or in the county where the defendant resides.

(c) An action brought under this section is in addition to any other penalty provided by law and may be brought concurrently with other actions to enforce this chapter.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-25

Sec. 25. A wholesale drug distributor that fails to allow an authorized person to enter and inspect a facility as provided in section 19 of this chapter commits a Class A misdemeanor. However, the offense is a Class D felony if the person has a prior unrelated conviction for an offense under this section.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-26

Sec. 26. A person that engages in the wholesale distribution of a legend drug without a license issued under this chapter commits a Class D felony.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-27

IC 25-26-14-27 Sec. 27. A wholesale drug distributor that fails to comply with the conditions described in section 17 of this chapter commits a Class D felony.

As added by P.L.182-1991, SEC.3.